COVERED ENTITY STATUS – RULE TWO

The privacy standard contains additional designations that covered entities can (or must) utilize to comply with Rule Two, Privacy. These descriptions will help begin discussions on how agencies view themselves under Privacy

1. Hybrid entity

Definition: means a single legal entity that is a covered entity and whose covered functions are not its primary functions. Components of a covered entity that perform covered functions are part of the health care component (HC Component).

Application: if most of what the Agency does is not related to paying or providing the cost of medical care, or paying or providing health care services, then the Agency is a Hybrid entity.

Effect: The parts of the Agency that are related to paying or providing medical or health care must be defined and separated from the non-health care related components of the Agency. The non-health care components are not required to comply with HIPAA privacy. Sharing of information between the Agency HC components and non-health care components is restricted.

164.504(a) – definition of hybrid entity and HC component.

164.504(b) – provider, plan, or clearinghouse applies only to HC Component(s) that perform those functions. Protected health information (PHI) applies only to information created or received by or on behalf of the HC component.

164.504(c)(1) - Covered entity must ensure that HC Component complies with applicable regulation.

164.504(c)(2) - Safeguard HC Component's use or disclosure of PHI to non- HC Components of the entity. Safeguard use of PHI by administrative and support units that perform functions for both components and ensure that PHI is used only for the HC Component.

164.504 (c)(3) – Covered entity must implement policies and procedures with respect to PHI to comply with HIPAA standards. Covered entity must designate the components that are part of the HC Component(s) and document the designation.

Government agencies specifically contemplated in the official comments.

Issues:

Is most of what Agency does related to health care functions?

Segregation of components and safeguard of information

Segregation of support functions for HC component and non- HC component

Use of information by non – HC components

Different standards/policies for same data

2. Affiliated covered entities.

Definition: legally separate covered entities that are affiliated may designate themselves as a single covered entity for purposes of this subpart (subpart E, Privacy). Must have either common control or common ownership.

Application: if the Agency shares common control or ownership with other, separate entities, then the entities may designate themselves as affiliated. State agencies are all executive agencies of the state.

Effect: affiliates are deemed "a single covered entity". Thus, the affiliate group would have one notice of privacy practices, one consent document, one privacy official, one complaint / information request point of contact. The designation must be documented. Minimum necessary use and disclosure of PHI still applicable.

Government agencies not specifically contemplated in the official comments.

Issues:

Are the Agencies affiliated with other entities? State agencies are under the common control of the Governor.

Feasibility of shared privacy notice and consent, and central contact

3. *Organized health care arrangement*

Definition: A clinically integrated care setting; An organized system of health care where participants hold themselves out to the public as participating in a joint arrangement; and participate in joint activities; or a group health plan and a health insurance issuer or HMO with respect to such group health plan, or group health plans maintained by the same plan sponsor.

Application:

Effect: Organized health care arrangements may have a joint consent, single notice of information practices, and may designate one privacy official. Each covered entity remains responsible for violations. Minimum use and disclosure still applies to sharing information between the entities.

Government agencies not specifically contemplated in the official comments.

Issues:

4. Joint Administration

Definition: (Official Comments, 82477). Where a public agency is required or authorized by law to administer a health plan jointly with another entity, we consider each agency to be a covered entity with respect to the health plan functions it performs.

Application: Unlike private sector health plans, public plans are often required by or expressly authorized by law to jointly administer health programs that meet the definition

of “health plan” under this regulation. In some instances the public entity is required or authorized to administer the program with another public agency. In other instances, the public entity is required or authorized to administer the program with a private entity. In either circumstance, we note that joint administration does not meet the definition of ‘business associate” in 164.501. Examples of joint administration include state and federal administration of the Medicaid and SCHIP program, or joint administration of a Medicare+Choice plan by the Health Care Financing Administration and the issuer offering the plan.

Effect: Each party is a covered entity with respect to the covered functions it performs in the joint administration of a health plan. Each entity must comply separately with the regulation. No business associate relationship is formed.

Issues:

Official Comments

Section 164.504 Pg 82639
We generally agree. We expect that in most cases, government agencies that run health plans or provide health care services would typically meet the definition of a "hybrid entity" under 164.504(a), so that such an entity would be required to designate the health care component or components that run the program or programs in question under 164.504(c)(3) and the rules would not apply to the remainder of the agency's operations under 164.504(b). In addition, we created an exception to the business associate contract requirement for government agencies who perform functions on behalf of other government agencies. . .

Section 164.504(a)-(c)--Health Care Component (Component Entities) Pg. 82637
…The health care component rules are designed for the situation in which the health care functions of the legal entity are not its dominant mission. Because some part of the legal entity meets the definition of a health plan or other covered entity, the legal entity as a whole could be required to comply with the rules below. However, in such a situation, it makes sense not to require the entire entity to comply with the requirements of the rules below, when most of its activities may have little or nothing to do with the provision of health care; rather, as a practical matter, it makes sense for such an entity to focus its compliance efforts on the component that is actually performing the health care functions. On the other hand, where most of what the covered entity does consists of covered functions, it makes sense to require the entity as a whole to comply with the rules. The provisions at §§ 164.504(a)-(c) provide that for a hybrid entity, the rules apply only to the part of the entity that is the health care component. At the same time, the lack of corporate boundaries increases the risk that protected health information will be used in a manner that would not otherwise be permitted by these rules. Thus, we require that the covered entity erect firewalls to protect against the improper use or disclosure within or by the organization. See § 164.504(c)(2).
The term "primary functions" in the definition of "hybrid entity" is not meant to operate with mathematical precision. Rather, we intend that a more common sense evaluation take place: is most of what the covered entity does related to its health care functions? If so, then the whole entity should be covered. Entities with different insurance lines, if not separately incorporated, present a particular issue with respect to this analysis. Because the definition of "health plan" excludes many types of insurance products (in the exclusion under paragraph (2)(i) of the definition), we would consider an entity that has one or more of these lines of insurance in addition to its health insurance lines to come within the definition of "hybrid entity," because the other lines of business constitute substantial parts of the total business operation and are required to be separate from the health plan(s) part of the business.
An issue that arises in the hybrid entity situation is what records are covered in the case of an office of the hybrid entity that performs support functions for both the health care component of the entity and for the rest of the entity. For example, this situation could arise in the context of a company with an onsite clinic (which we will assume is a covered health care provider), where the company's business office maintains both clinic records and the company's personnel records. Under the definition of the term "health care component," the business office is part of the health care component (in this hypothetical, the clinic) "to the extent that" it is performing covered functions on behalf of the clinic involving the use or disclosure of protected health information that it receives from, creates or maintains for the clinic. Part of the business office, therefore, is part of

the health care component, and part of the business office is outside the health care component. This means that the non-health care component part of the business office is not covered by the rules below. Under our hypothetical, then, the business office would not be required to handle its personnel records in accordance with the rules below. The hybrid entity would be required to establish firewalls with respect to these record systems, to ensure that the clinic records were handled in accordance with the rules.

…If a particular organizational unit performs both excepted benefits functions and covered functions, the activities associated with the excepted benefits program may not be part of the health care component. For example, an accountant who works for a covered entity with both a health plan and a life insurer would have his or her accounting functions performed for the health plan as part of the component, but not the life insurance accounting function. See § 164.504(c)(2)(iii). We require this segregation of excepted benefits because HIPAA does not cover such programs, policies and plans, and we do not permit any use or disclosure of protected health information for the purposes of operating or performing the functions of the excepted benefits without authorization from the individual, except as otherwise permitted in this rule.

In § 164.504(c)(2) we require covered entities with a health care component to establish safeguard policies and procedures to prevent any access to protected health information by its other organizational units that would not be otherwise permitted by this rule. We note that Sec. 1173 (d)(1)(B) of HIPAA requires policies and procedures to isolate the activities of a health care clearinghouse from a "larger organization" to prevent unauthorized access by the larger organization. This safeguard provision is consistent with the statutory requirement and extends to any covered entity that performs "non-covered entity functions" or operates or conducts functions of more than one type of covered entity.

Because, as noted, the covered entity in the hybrid entity situation is the legal entity itself, we state explicitly what is implicitly the case, that the covered entity (legal entity) remains responsible for compliance vis-a-vis subpart C of part 160. See § 164.504(c)(3)(i). We do this simply to make these responsibilities clear and to avoid confusion on this point. Also, in the hybrid entity situation the covered entity/legal entity has control over the entire workforce, not just the workforce of the health care component. Thus, the covered entity is in a position to implement policies and procedures to ensure that the part of its workforce that is doing mixed or non-covered functions does not impermissibly use or disclose protected health information. Its responsibility to do so is clarified in § 164.504(c)(3)(ii).

Section 164.504(d) - Affiliated Entities, Pg 82503

Some legally distinct covered entities may share common administration of organizationally differentiated but similar activities (for example, a hospital chain). In § 164.504(d) we permit legally distinct covered entities that share common ownership or control to designate themselves, or their health care components, together to be a single covered entity. Common control exists if an entity has the power, directly or indirectly, significantly to influence or direct the actions or policies of another entity. Common ownership exists if an entity or entities possess an ownership or equity interest of 5 percent or more in another entity.

Such organizations may promulgate a single shared notice of information practices and a consent form. For example, a corporation with hospitals in twenty states may designate itself as a covered entity and, therefore, able to merge information for joint marketplace analyses. The requirements that apply to a covered entity also apply to an affiliated covered entity. For example, under the minimum necessary provisions, a

hospital in one state could not share protected health information about a particular patient with another hospital if such a use is not necessary for treatment, payment or health care operations. The covered entities that together make up the affiliated covered entity are separately subject to liability under this rule. The safeguarding requirements for affiliated covered entities track the requirements that apply to health care component.

Health Plan comment, Pg. 82479

…We note that in certain instances eligibility for or enrollment in a health plan that is a government program providing public benefits, such as Medicaid or SCHIP, is determined by an agency other than the agency that administers the program, or individually identifiable health information used to determine enrollment or eligibility in such a plan is collected by an agency other than the agency that administers the health plan. In these cases, we do not consider an agency that is not otherwise a covered entity, such as a local welfare agency, to be a covered entity because it determines eligibility or enrollment or collects enrollment information as authorized by law. We also do not consider the agency to be a business associate when conducting these functions as we describe further in the business associate discussion above.